

K082573

510(k) Summary

1. Applicant's Name and Address Sargon Enterprises, Inc.
16101 Ventura Blvd. (Suite 350)
Encino, CA 91436 JUL 2

JUL 21 2010

Submitted by: Daniel J. Manelli
Manelli & Fisher, P.L.L.C.
5335 Wisconsin Avenue NW (Suite 440)
Washington, DC 20016
Telephone: 202-885-5548

2. Name of the Device:

Trade Name: Sargon Non-Expandable Dental Implant™
Common Name: Endosseous dental implant
Classification Name: Endosseous dental implant

3. Substantial Equivalence:

Strauman ITI (K012757, K003271 and K033984)
Sargon implants (K930071, K961005 and K981141)

4. Description of the Device

The Sargon Non-Expandable implant is a root form endosseous dental implant (FDA classification code DZE). It has been placed in class 2 per 21 CFR 872.3640. The device is fabricated from titanium alloy meeting the specifications of ASTM F136. It is available in lengths of 8, 10, 13, and 16mm and diameters of 4.3 and 5.1mm. The surface is grit blasted and acid etched. The device is provided sterile. Sterility is achieved by gamma radiation pursuant to ISO 11137 to provide a sterility assurance level (SAL) of 10^{-6} .

5. Intended use of the device

The device is indicated for immediate placement or delayed placement in the bone of the upper or lower jaw to support prosthetic devices such as artificial teeth, crowns, bridges or overdentures in partially or fully edentulous patients and to restore the patient's chewing function. This device is not indicated for immediate loading.

6. Basis for Substantial Equivalence

The Sargon Non-Expandable Dental Implant is substantially equivalent to the above identified Strauman implants from the standpoint of material composition, implant dimensions (e.g., Strauman K033984; lengths 8, 10, 13, 16; diameters 3.3, 4.1, 4.8), surface treatment and indications for use. It is also substantially equivalent to the previously cleared Sargon expandable implant. It incorporates no novel technological characteristics, unique indications or materials as compared with the predicate devices.

revised 7/14/10



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JUL 21 2010

Sargon Enterprises, Incorporated
C/O Mr. Daniel J. Manelli
Manelli & Fisher, P.L.L.C.
5335 Wisconsin Avenue NW, Suite 440
Washington, DC 20015

Re: K082573

Trade/Device Name: Sargon Non-Expandable Dental Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 15, 2010
Received: July 16, 2010

Dear Mr. Manelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082573

Device Name: Sargon Non-Expandable Dental Implant

Indications for Use:

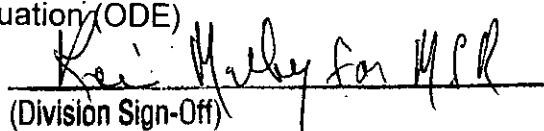
The Sargon Non-Expandable Dental Implant is indicated for immediate placement or delayed placement in the bone of the upper or lower jaw to support prosthetic devices such as artificial teeth, crowns, bridges or overdentures in partially or fully edentulous patients and to restore the patient's chewing function. This device is not indicated for immediate loading.

Prescription Use X
(Part 21 CFR 801 Subpart D) AND/OR
(21 CFR 801 Subpart C)

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 082573